

NOV 13 1997

Department of Health and Human Services
June 30, 1997

K972510

APPENDIX B

Summary of Safety and Effectiveness

The Pivotal instrument is substantially equivalent to like devices in commercial distribution. Pivotal instruments perform the same function and have the same intended use as instruments distributed by Ethicon, United States Surgical Corporation (USSC), and Richard-Allan Medical.

The Pivotal instruments and similar currently marketed devices are intended to cut, grasp, manipulate, and coagulate tissue during surgical procedures. The similar marketed endoscopic devices are designed to be used with monopolar electrosurgery and are disposable devices supplied sterile to the user. These devices are available in a variety of blade and jaw configurations. These devices have similar thermoplastic ringed handles that open and close the jaws. The grasper devices are all equipped with a ratchet mechanism that allows the tissue to be held in the jaws without the need for applying constant pressure on the ringed handles.

The Auto Suture Endo Instruments, Auto Suture Reticulator Instruments, the Endopath Instruments, and the Reflex 5mm Laparoscopic Scissors are indicated for a variety of endoscopic procedures. The Ethicon PowerStar is indicated for general open surgical procedures. The Pivotal instrument is indicated for both open and endoscopic surgical procedures. This difference will not affect safety, effectiveness, or overall function of this type of device.

The Pivotal instrument and the endoscopic substantially equivalent devices are available in various tip configurations including scissors, dissectors, and graspers. The tip configurations of the Pivotal instruments are equivalent to devices being distributed by Ethicon and USSC.

The Pivotal instrument and other substantially equivalent devices contain components of similar materials; such as stainless steels, thermoplastics, braided fiberglass/epoxy, and Teflon®. The epoxy braided fiberglass material is used on Richard-Allan's currently marketed Reflex STR Trocar. The Teflon® material is used on Richard-Allan's currently marketed Reflex 5mm Laparoscopic Scissors.

The Pivotal instrument complies with the applicable safety, performance, and labeling requirements of the American National Standard Institute and the Association for the Advancement of Medical Instrumentation ANSI/AAMI HF18-1993 Standard for Electrosurgical Devices and ANSI/AAMI ESI-1993 Safe Current Limits for Electromedical Apparatus.

The method of sterilization and the method used to validate our sterilization process are in compliance with the ANSI/AAMI/ISO 1135-1994 Medical Devices—Validation and routine control of ethylene oxide sterilization.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Julie Powell
Quality Assurance and Regulatory Affairs Director
Richard - Allan Medical
8850 M89, Box 351
Richland, Michigan 49083-0351

Re: K972510
Trade Name: Pivotal Grasper, Pivotal Dissector, and Pivotal Scissors
Regulatory Class: II
Product Code: GEI
Dated: October 7, 1997
Received: October 8, 1997

Dear Ms. Powell:

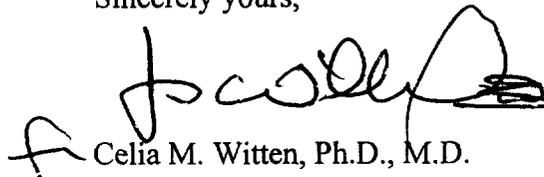
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', is written over the typed name.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

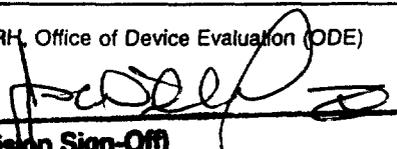
Device Name: Pivotal Grasper, Pivotal Dissector, and Pivotal Scissor

Indications for Use:

The Pivotal devices are sterile, disposable, general surgical instruments for use in endoscopic or open surgical procedures to dissect, transect, manipulate, coagulate, and/or grasp tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE — CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices
510(k) Number

K972510

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)